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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,692	07/28/2003	Brent L. Atkinson	CRM-P15F/P	5172

7590 12/15/2006

DENTSPLY INTERNATIONAL INC.
570 West College Avenue
York, PA 18405-0872

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,692	ATKINSON ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1 – 14 and 19 in the reply filed on September 29, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore the restriction is considered proper and is made FINAL.

Claims 15 – 18 are withdrawn from consideration as being drawn to non-elected subject matter. It is noted that applicant requested that claims 15 – 18 to be canceled in the response, however a new claim set canceling these claims was not submitted with the response. Therefore, the claims are considered to be withdrawn, not canceled. Claims 1 – 19 are pending; claims 15 – 18 are withdrawn; claims 1 –1 4 and 19 and have been considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 14 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a bone repair material however are rendered vague and indefinite for reciting "natural bone-like mineral" because the phrase has not adequately been defined by the claim language or specification.

Claim 1 and its dependents are further indefinite because it is unclear what amount and concentration and molecular weight is required of the gel component of the composition.

In claim 5, line 1, "said carrier material" lacks sufficient antecedent basis.

Claims 7, 13, 14 and dependents thereof, are rendered vague and indefinite for reciting collagen sequences from an issued patent and continuations thereof, because it is unclear what applicant intends the claims to encompass. The specification fails to identify these sequences by incorporation thereof, or by name, thus it is unclear what collagens are specifically being claimed.

Claim 8 is rendered vague and indefinite for reciting "said amount of particulate present dependent on its density" because it is unclear how the amount adjusts relative to the density of the particulate.

In claims 9 and 11, line 2, "the putty compositions" lacks sufficient antecedent basis.

In claim 12, line 1, "the bone repair graft" lacks sufficient antecedent basis.

Claims 13 and 14 are confusing because it is unclear if the composition further comprises the collagen, or rather comprises the collagen.

In claims 19, line 1, "the concentration of PEPGEN P-15" lacks sufficient antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 3 – 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gertzman et al. (US 6030635 A).

Applicant claims a bone repair material comprising a porous, resorbable particulate derived from anorganic or natural bone mineral, or synthetic hydroxyapatite; and a resorbable carrier gel forming a putty like formulation; wherein the gel has a molecular weight and concentration sufficient to facilitate bone repair and minimalize migration and expansion of the material. The particulate is porous hydroxyapatite derived from lime containing algae, with a particle size of 300 – 1000 um; the gel comprises a polysaccharide; the gel comprises hyaluronic acid, derivatives thereof, hydroxypropyl cellulose, or mixtures thereof.

Gertzman teaches a putty for repairing bone (abstract) comprising bone powder with a particle size of about 100 – 850 um and high molecular weight gel (abstract). The bone particles are 100 – 450 um (col.4 line 63-65) and are combined with hyaluronate (hyaluronic acid) with molecular weights of 7x10^5 – 3x10^6 daltons (col.5 line 1-10). Other compositions may include hyaluronic acid and up to 75% bone particles with 250 – 850 um diameters (col.5 line 57-61). Additional substances can be added to the bone putty such as collagen, hydroxyapatite, or peptide (col.5-6).

Although the reference does not teach the hydroxyapatite is derived from lime containing algae, this limitation is considered to be a product by process type limitations. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefor the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzman.

Applicant claims a bone repair material comprising a porous, resorbable particulate derived from anorganic or natural bone mineral, or synthetic hydroxyapatite; and a resorbable carrier gel forming a putty like formulation; wherein the gel has a molecular weight and concentration sufficient to facilitate bone repair and minimalize migration and expansion of the material. The gel comprises a polysaccharide; hyaluronic acid, derivatives thereof, hydroxypropyl cellulose, or mixtures thereof; the gel is hyaluronic acid with a molecular weight of 0.7 – 2 x10^6 daltons and a concentration of 45 – 64 mg/cc in the putty. Applicant claims a bone repair material for dental bone repair comprising 30 – 75% of a porous, resorbable, hydroxyapatite or anorganic done derived particulate; and 25 – 70% of a hyaluronic acid gel; wherein the material is a moldable putty and the amount of particulate is dependent on its density

Gertzman teaches a putty for repairing bone (abstract) comprising bone powder with a particle size of about 100 – 850 um and high molecular weight gel (abstract). The bone particles are 100 – 450 um (col.4 line 63-65) and are combined with hyaluronate (hyaluronic acid) with molecular weights of 7x10^5 – 3x10^6 daltons (col.5 line 1-10). Other compositions may include hyaluronic acid and up to 75% bone particles with 250 – 850 um diameters (col.5 line 57-61). Additional substances can be added to the bone putty such as collagen, hydroxyapatite, or peptide (col.5-6).

Gertzman does not teach the composition comprising the claimed concentrations or percents of components. However, Gertzman teaches the carrier gel has a molecular weight high enough to provide a malleable (moldable) putty and be present in low amounts (col.4 line 8-23). Gertzman additionally provides examples with varying amounts of particles and carrier gel, dependent on particle size and molecular weights (see examples), to ensure a putty formulation. Thus, as evidenced by Gertzman the amounts and concentrations of the components are result effect variables. Therefore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of ingredients in the composition of Gertzman as a matter of routine practice. Moreover, in following the teachings of Gertzman, one of ordinary skill in the art would have been motivated by Gertzman to optimize the amounts of gel and particulates with a reasonable expectation for successfully obtaining an effective putty like material for repairing bone.

9. Claims 1 – 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertzman in view of Tofe (US 2003/0143283 A1).

Applicant claims a bone repair material comprising a porous, resorbable particulate derived from anorganic or natural bone mineral, or synthetic hydroxyapatite; and a resorbable carrier gel forming a putty like formulation; wherein the gel has a molecular weight and concentration sufficient to facilitate bone repair and minimalize migration and expansion of the material. The particulate is bovine derived and has a particle size of 250 – 1000 um; the particulate is porous hydroxyapatite derived from lime containing algae, with a particle size of 300 – 1000 um. The gel comprises a polysaccharide; comprises hyaluronic acid, derivatives

thereof, hydroxypropyl cellulose, or mixtures thereof; is hyaluronic acid with a molecular weight of 0.7 – 2 x10^6 daltons and a concentration of 45 – 64 mg/cc in the putty. The bone repair material further comprises a synthetic type I collagen with a particular polypeptide sequence. The particulate has a density of 1.1 – 1.3 g/cc and the putty comprises 50 – 60 % particulate and 40 – 50 % hyaluronic acid gel; the material comprises about 55% particulate and about 45% hyaluronic acid gel; the particulate has density of 0.45 – 0.65 g/cc and the putty comprises 35 – 40% particulate and 60 – 65% hyaluronic acid gel. The carrier gel is hydroxypropyl cellulose or methylcellulose. The material further comprises a P15 polypeptide collagen with a particular sequence bound to porous hydroxyapatite derived from lime containing algae, with a diameter of about 300 – 1000 um, suspended in hydroxylpropyl cellulose or hyaluronic acid gel; the PEPGEN P15 is present in an amount of at least 800 mg/cc. Applicant additionally claims a bone repair material for dental bone repair comprising 30 – 75% of a porous, resorbable, hydroxyapatite or anorganic done derived particulate; and 25 – 70% of a hyaluronic acid gel; wherein the material is a moldable putty and the amount of particulate is dependent on its density. The material further comprises a P15 polypeptide with a particular sequence that is bound to xenogeneic bone particulate with about 200 – 500 mm diameter, suspended in the carrier gel.

Gertzman teaches a putty for repairing bone (abstract) comprising bone powder with a particle size of about 100 – 850 um and high molecular weight gel (abstract). The bone particles are 100 – 450 um (col.4 line 63-65) and are combined with hyaluronate (hyaluronic acid) with molecular weights of 7x10^5 – 3x10^6 daltons (col.5 line 1-10). Other compositions may include hyaluronic acid and up to 75% bone particles with 250 – 850 um diameters (col.5 line

57-61). Additional substances can be added to the bone putty such as collagen, hydroxyapatite, or peptide (col.5-6).

Although the reference does not teach the hydroxyapatite is derived from lime containing algae, this limitation is considered to be a product by process type limitations. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Gertzman does not teach the putty composition wherein the particulate is bovine or wherein the collagens and peptides have the claimed collagen sequences. However, at the time of the claimed invention, the instant materials were well known and used in the art for bone repair putty composition. In support, Tofe teaches a composite for repairing bone, comprising hyaluronate (hyaluronic acid) and bovine bone particulate or hydroxyapatite (abstract) and peptides such as those claimed (0014). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the claimed particulates and collagens in the putty of Gertzman since they were well known and used for their claimed purpose, as evidenced by Tofe.

Gertzman does not teach the composition comprising the claimed concentrations or percents of components. However, Gertzman teaches the carrier gel has a molecular weight high enough to provide a malleable (moldable) putty and be present in low amounts (col.4 line 8-23).

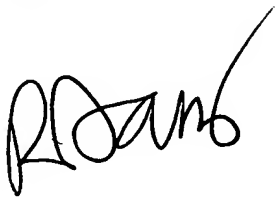
Gertzman additionally provides examples with varying amounts of particles and carrier gel, dependent on particle size and molecular weights (see examples), to ensure a putty formulation. Thus, as evidenced by Gertzman the amounts and concentrations of the components are result effect variables. Therefore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of ingredients in the composition of Gertzman as a matter of routine practice. Moreover, in following the teachings of Gertzman, one of ordinary skill in the art would have been motivated by Gertzman to optimize the amounts of gel and particulates with a reasonable expectation for successfully obtaining an effective putty like material for repairing bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



December 8, 2006